

# Element<sup>®</sup> Multi


Glucose & Cholesterol Measuring System


## Instruction for Use



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## Dear Element<sup>®</sup> Multi glucose and cholesterol measuring system Owner

Thank you for choosing Element<sup>®</sup> Multi glucose and cholesterol measuring system. This instruction for use includes important information you need to know about Element<sup>®</sup> Multi glucose and cholesterol measuring system. Please read it carefully.

Our goal for Element<sup>®</sup> Multi glucose and cholesterol measuring system is attributed to provide the best quality healthcare products coupled with superior customer service.

## Intended For Use

Element<sup>®</sup> Multi glucose and cholesterol measuring system is intended for self testing and for outside the body (in vitro diagnostic use only). Element<sup>®</sup> Multi is used to test glucose, total cholesterol, LDL-cholesterol (often called bad cholesterol), triglycerides and HDL-cholesterol (often called good cholesterol).

Additionally, Element<sup>®</sup> Multi glucose test is plasma-calibrated to allow comparison of results with the laboratory method.

This meter is available in two types of strips: one type of strips measures glucose level by the method of electrochemistry and the others measure cholesterol by the spectroscopy method.

## Test Principle

Element® Multi glucose and cholesterol measuring system has two kinds of test principle according to test items: one for blood glucose and the others for cholesterol.

Cholesterol test result is based on a reading reflection of density. When the blood is applied, the color is changed in the test area through an enzyme reaction. The meter records this color change and converts the measurement signal to the displayed results by using the data previously entered by the code. The deeper color is, the higher level is.

Glucose in the blood sample will react to the electrodes in the glucose test strip, generating an electrical current that will stimulate a chemical reaction. This reaction is measured by Element® Multi meter and displayed as your blood glucose result.

## How to use Instructions For Use

This guide includes all the information you need to use Element® Multi for self-testing. For additional information and specific information for each individual test, please make sure you read the strip instructions for use included with the test strips.

If you need our help or have some questions, please contact the local representative. Customer Service assistance is available 09:00 AM - 06:00 PM, Monday-through Friday.

For questions or assistance with Element® Multi call :  
infopia Customer Service  
Hours : 09:00 AM - 06:00 PM  
Monday - Friday  
Tel. +82-31-460-0300  
Fax. +82-31-460-0401  
Email : sales@infopia21.com

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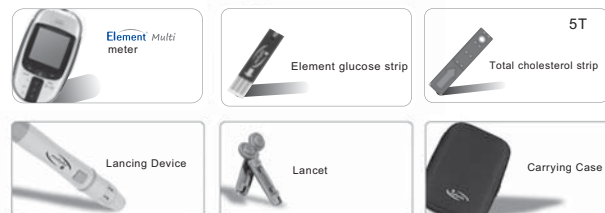
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## Element® Multi Testing System Kit Contents



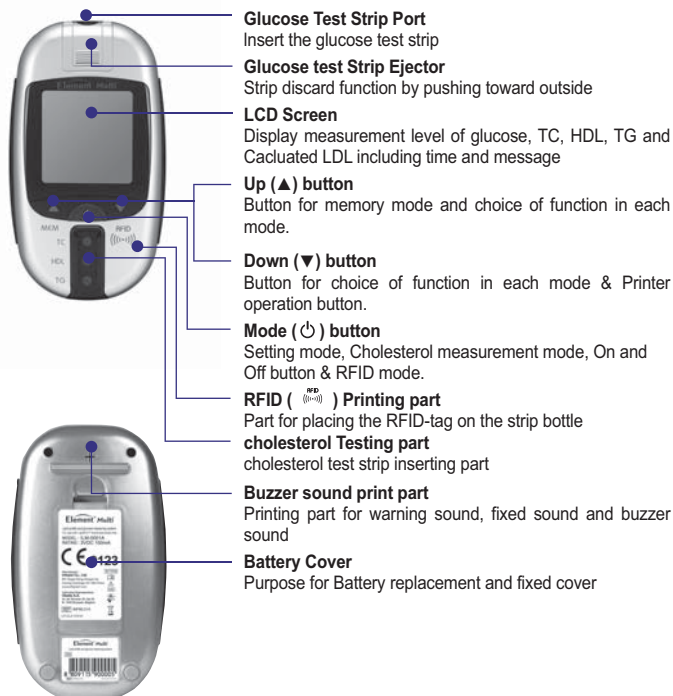
- |                                       |                              |
|---------------------------------------|------------------------------|
| 1. Element® Multi Meter               | 8. Lancets                   |
| 2. Element® blood glucose test strips | 9. Carrying bag              |
| 3. Total cholesterol test strip       | 10. LipidProfile Check strip |
| 4. Capillary rods                     | 11. Warranty card            |
| 5. User manual                        | 12. Log book                 |
| 6. Quick manual                       | 13. 2 AAA batteries          |
| 7. Lancing device                     |                              |

Element® Multi system has been sealed to protect the contents.  
If you find your seal broken, please return it to the place of purchase.

Required but not provided

- Element® Multi Brand Control Solutions
- LipidProfile test strip
- HDL-Cholesterol test strip
- Triglyceride test strip

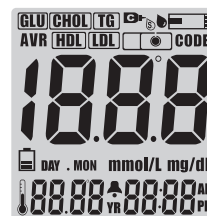
## Element® Multi Testing Meter



### Caution

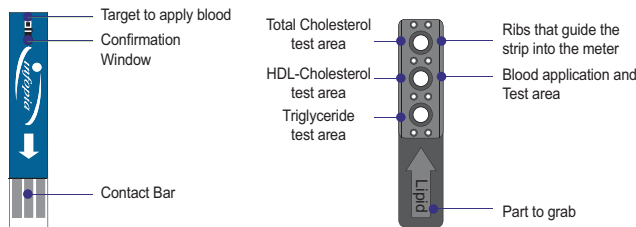
1. Do not use Element® Multi meter in a dry environment, especially if synthetic materials are present. Synthetic clothes, carpets, etc., may cause damaging static discharges in a dry environment.
2. Do not use Element® Multi meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters, or other electronic or electrical equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

## Element® Multi Testing Meter Display

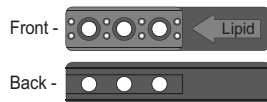


<b>GLU</b>	Blood Glucose
<b>CHOL</b>	Total cholesterol
<b>TG</b>	Triglyceride
<b>HDL</b>	HDL-cholesterol
<b>LDL</b>	LDL-cholesterol
	Blood insertion for glucose test
	Blood insertion for cholesterol test
	Serum
	Sample blood
<b>CODE</b>	Displaying code number of Test Strips
	Low batteries
	Alarm
<b>mmol/L mg/dL</b>	Testing unit
	Temperature & date of test
	Hour & Date of test
<b>AVR</b>	Average Test Results(only for glucose)
	Control Solution Symbol
<b>DAY . MON</b>	Day & Month
<b>YR</b>	Year

## Element® Multi Test Strip Information

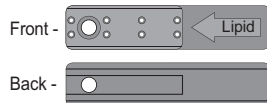


### 1. Profile test strip



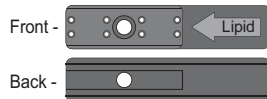
This test strip in black enables to test TC, HDL, TG and calculated LDL.

### 2. Total Cholesterol test strip



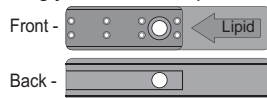
This test strip in red is for Total Cholesterol.

### 3. HDL-Cholesterol test strip



This test strip in blue is for HDL-Cholesterol.

### 4. Triglyceride test strip



This test strip in green is for Triglyceride.

## Element® Multi Test Strip Information

### 5. Glucose test strip



This test strip is for glucose.

※ The Element® Multi glucose test strip is equal to Element™ blood glucose test strip. The Element™ glucose test strip can be used with an Element® Multi meter and Element™ meter for glucose measuring test.

#### Caution

1. Store the Element® Multi test strip vials in a cool and dry place. Keep out of direct sunlight. Do not freeze.
2. Store test strips in their original vial only. Do not mix the test strips in new vials or in any other container.
3. Immediately replace the vial cap and close tightly after picking out the Element® Multi test strips.
4. Make a note of the discard date which is three months from the date you first open a new vial of strips. Do not use Element® Multi test strips and vial after the discard date.
5. Avoid getting dirt, food, and water on the test strip. Do not handle test strips with wet hands.
6. Do not use the test strips after the expiry date printed on the package or vial since it may cause inaccurate results.
7. Do not bend, cut, or alter the test strip.
8. Element® Multi test strips are for single use only. Do not re-use.
9. Do not test at the following temperature condition:
  - Cholesterol strips : below 18°C (64°F) or above 30°C (86°F).
  - glucose strip : below 10°C (50°F) or above 40°C (104°F)
10. Do not test with humidity below 10% or above 90%.
11. Refer to additional information in the Element® Multi test strip package.
12. Avoid getting dirt, food, and water on the color-coding label (backside of glucose test strip).
13. Discard the used test strips carefully according to the local regulations.

## Element® Multi Test Strip Information

### LIMITATIONS OF SYSTEM for cholesterol test

Profile Test Strips provide accurate results when the following constraints are observed:

- Do not use neonate samples

Please note the following interferences that may affect the results:

- Extremes in hematocrit may affect test results. Hematocrit levels less than 30 % may cause falsely high reading and hematocrit levels greater than 55 % may cause falsely low reading.
- Interferences: Acetaminophen, uric acid, ascorbic acid (vitamin C), and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.
- Only EDTA and Heparin containing tubes are recommended as an anticoagulant tube.
- Total cholesterol may be decreased by dopamine and gentisic acid.
- HDL-cholesterol may be decreased by dopamine.
- Triglyceride may be decreased by dopamine and Methyl dopa.

### Performance Characteristics:

The performance of the cholesterol test strip has been evaluated in laboratory and in clinical tests (Please refer to strip instructions for use for more details).

Testing Range: The test range of Element® Multi is 100 ~ 400 mg/dL (2.59-10.36mmol/L) for total cholesterol, 25~80mg/dL (0.65-2.08mmol/L) for HDL-cholesterol and 70~600 mg/dL (0.80-6.86mmol/L) for Triglyceride.

### Accuracy

#### 1-1. Total Cholesterol

Sample Type	Regression line	slope	y-interceptor	R <sup>2</sup>
Capillary	Y=0.9871x+2.2856	0.9871	2.2856	0.9842

#### 1-2. HDL-Cholesterol

Sample Type	Regression line	slope	y-interceptor	R <sup>2</sup>
Capillary	Y=0.9732x+1.4038	0.9732	1.4038	0.9656

#### 1-3. Triglyceride

Sample Type	Regression line	slope	y-interceptor	R <sup>2</sup>
Capillary	Y=0.9975x+1.3080	0.9975	1.3080	0.9816

#### 1-4. LDL-Cholesterol

Sample Type	Regression line	slope	y-interceptor	R <sup>2</sup>
Capillary	Y=0.9257x+8.4998	0.9257	8.4998	0.8815

### Precision

- Precision Results for Human Serum samples tested for 20 days.

#### 2-1. Total cholesterol

Mean Conc (mg/dL)	178.6	271.5
SD (mg/dL)	8.4	10.4
CV (%)	4.7	3.8

#### 2-2. HDL-cholesterol

Mean Conc (mg/dL)	49.8	25.2
SD (mg/dL)	3.0	1.6
CV (%)	5.9	6.3

#### 2-3. Triglyceride

Mean Conc (mg/dL)	120.8	267.4
SD (mg/dL)	5.3	10.2
CV (%)	4.4	3.8

- Precision Results for Control Solutions.

#### 2-1. Total cholesterol

Mean Conc (mg/dL)	150.3	250.6
SD (mg/dL)	2.2	3.6
CV (%)	1.5	1.4

#### 2-2. HDL-cholesterol

Mean Conc (mg/dL)	60.1	30.0
SD (mg/dL)	2.1	1.4
CV (%)	3.5	4.7

#### 2-3. Triglyceride

Mean Conc (mg/dL)	120.5	250.5
SD (mg/dL)	2.9	2.8
CV (%)	2.4	1.4

## Element® Multi Test Strip Information

### LIMITATIONS OF SYSTEM for glucose test

*The Element® Multi Glucose Test Strips provide accurate results when the following constraints are observed:*

- Do not use neonate samples.
- Inaccurate results may occur when in shock, hypotensive, hyperglycemic, or hyperosmolar state with or without ketosis.
- Glucose test strips used above altitudes of 10,000 feet will have an effect on test results.

*Please note the following interferences that may affect test results:*

- **Element® Multi Glucose** test strip results can be used with hematocrit levels in the range of 20% to 60%. If the hematocrit range is out of the range(20%–60%), then the test results may be lower or higher than actual value.
- Interferences: Acetaminophen, Uric and, Ascorbic acid (Vitamin C), and other reducing substances when occurring in normal blood or normal therapeutic concentrations do not significantly affect results. However, abnormally high concentrations may cause inaccurately high results.
- Lipemic samples; Cholesterol up to 500 mg/dL or triglyceride up to 3000mg/dl do not significantly affect the results. Values beyond these levels should be interpreted with caution.
- Blood samples that contain a high concentration of dissolved oxygen may lower the test result.
- EDTA containing tube is recommended as an anticoagulant tube.

### Performance Characteristics:

The performance of the glucose test strips has been evaluated in laboratory and in clinical tests (Please refer to strip instructions for use for more details).

**Measurement Range:** The measurement range of the Element® Multi Glucose Testing is 10 to 600 mg/dL (0.6–33.3mmol/L).

### Accuracy:

The accuracy results obtained with the Element® Multi glucose and cholesterol measuring system were compared to glucose results obtained with the Hitachi meter 747, a laboratory instrument. Glucose levels were measured on 160 patients at three different clinical centers.

System accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)

Within ± 5mg/dL (within ± 0.28 mmol/L)	Within ± 10mg/dL (within ± 0.56 mmol/L)	Within ± 15mg/dL (within ± 0.83 mmol/L)
20/28(71%)	26/28 (93%)	28/28 (100 %)

System accuracy results for glucose concentration ≥ 75 mg/dL(4.2 mmol/L)

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	Within ± 20mg/dL
76/132(58%)	111/132(84%)	128/132 (97%)	132/132(100%)

### Precision:

Precision Results for venous blood samples.

Mean (mg/dL)	40	81	135	233	350
CV (%)	3.7	2.7	3.1	3.3	1.8

Precision Results for control solutions.

Mean (mg/dL)	47	106	307
CV (%)	3.3	3.1	3.1



## Setting Your Meter

### Battery Use

The Element®Multi requires two(2) AAA 1.5 volt alkaline batteries.

#### *When to replace the batteries:*

The meter will give you an indication on the display that the batteries need to be changed. When the battery icon is displayed, please change the batteries to high quality alkaline batteries. It is recommended to keep a spare set of batteries on hand. To extend battery life, remove the test strip as soon as a result is displayed.

#### *How to install /replace the batteries:*

1. Open the battery cover on the back of the Element®Multi.
2. Remove old batteries from the compartment and safely discard.
3. Insert the new batteries into the battery compartment as marked on the inside compartment.
4. Close the battery cover. To make sure the batteries were installed correctly, push either one of the two buttons on the front of the meter to turn the Element®Multi on.

#### <Follow Action>

1. Check your meter with the control solution.
2. Perform your test again.

### Caution



Remove both batteries from the battery compartment and dispose of them according to your institution's guidelines.

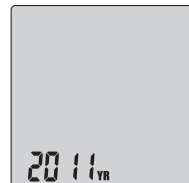
## Setting Your Meter




### Setting Mode

It is recommended to set your Element®Multi meter properly before using.






The meter enters setting mode with a beep sound by pressing the mode (  ) button for 3 or more seconds in the stand-by status. Press Mode (  ) button for the next step.



By pressing Up(  ) or Down (  ) button, adjust year and press Mode (  ) button.

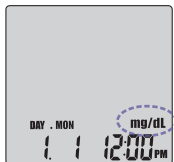


By pressing UP(  ) or Down (  ) button, adjust date, month and time, and then press Mode (  ) button.

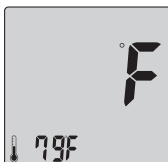
### Caution

Make sure that the date and time are set properly to enable your data to be stored and downloaded properly.

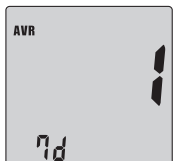
## Setting Your Meter



By pressing Up(▲) or Down(▼) button, select testing unit and press Mode ( ) button.



By pressing Up(▲) or Down(▼) button, select temperature unit and press Mode ( ) button.



By pressing Up(▲) or Down(▼) button, select average date and press Mode ( ) button.

**Note :** This average date is applied to glucose testing only.



By pressing Up(▲) or Down(▼) button, select Alarm ON/OFF and press Mode ( ) button. If you select Alarm ON, you can set the time by pressing Up(▲) or Down(▼) button, and press Mode ( ) button(you can set 2 alarms).



By Pressing ▲▼, select print ON/OFF and press Mode( ). If you select 'ON' and press Mode( ) button to activate it. If you select print, this setting mode is completed.

## Checking the system with control solution

### Quality control by control solution

Control testing, also known as quality control testing, is used to ensure all the parts of the test system are working properly together and the test results are accurate and reliable within the limits of the system. Contact customer support of local representative.

The users should follow their facility's policies on when controls should be tested (for example: with each new test strip lot; monthly as a continued check on storage conditions; whenever issues (storage, operator, or other) are identified or there are questions about the results).

### The control solution should be used

- Whenever you suspect the meter or test strip is not functioning properly.
- If your blood glucose test results are not consistent with your symptoms or if you think they are not accurate.
- If you have dropped the meter
- For quality control at the point of care
- For teaching or learning the system

### Note:

The Element® Multi Control Solutions are sold separately. The TC(Level 1, Level 2), TG(Level 1, Level 2) and HDL (Level 1, Level 2) control solutions can be obtained.

## Checking the system with control solution

### Caution

Please check the expiry date on the instructions for use provided with each control solution.

Total Cholesterol strip or profile test strip in Total Cholesterol test area should be used only Total Cholesterol control level 1, level 2. HDL Cholesterol strip or profile test strip in HDL Cholesterol test area should be used only HDL Cholesterol control level 1, level 2.

Triglyceride strip or profile test strip in triglyceride test area should be used only triglyceride control level 1, level 2.

Glucose test strip should be used only glucose control solution Low, Normal and High.


It is recommended that the control solution is stored at room temperature before testing.

### • Profile test

#### Testing procedure


1. Insert the test strip and press mode(  ) button.



2. Place the RFID-tag on the strip vial to the area of the RFID symbol (  ) on the meter.



### Caution



The radiation of RFID (  ) recognition is within 2cm.

The meter will revert back to stand-by status if there is no operation within 5 seconds.

## Checking the system with control solution

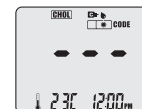
3. Check the code number on the display of the meter with that on the strip vial.



4. Press Up(  ) button and the meter displays the symbol of control solution(  ).



5. In 5 seconds the symbol of sample blood is blinking.



6. Place a drop of solution on a clean and dry surface (for example: the lid of your test strip vial).



7. Apply the prepared control solution to the test strip by using capillary rod.



8. Apply the control solution to the test area.

**Caution** : If you want to test all three test items (TC, HDL and TG), please collect the control solution with each capillary rod.



9. The test results will be displayed in 2 minutes.

**Caution** : Whenever you change the test strip vial, Please follow the code recognition procedure.



## Checking the system with control solution

### • Glucose test

#### Testing procedure

1. Shake the control solution before use.




2. Discard the 1<sup>st</sup> drop of control solution, this will eliminate any residue.



3. Place a drop of control solution on a clean and dry surface(ex. The lid of the test strip vial).



4. Insert a test strip into the port firmly and press Up(▲) button. The symbol of control solution (  ) will appear on the display of meter. This will allow you to differentiate between a control solution test and an actual blood test for future reference.



5. Apply the test strip to the control solution.



## Checking the system with control solution

6. Results appear in 3 seconds. Compare the result to the range printed on the test strip vial, the results should fall within that range.



### Testing tips:

- Please make a test after reading the instructions for use of control solution thoroughly.
- Keep clean of the test area on the meter.
- Keep test strips and control solutions in proper condition according to the instructions for use provided, such as expiry date, storage condition and so forth.
- Before testing, make sure that the test strips and the meter for lipid profile are at the temperature of 18-30°C(64-86°F) and those for glucose at 10-40°C(50-104°F).

### Caution

If your control solution test result is out of range, please follow the next steps before contacting customer support:

- Check the expiry dates on all the products you are using.
- Try another control solution test.
- If this test result is out of range, try another control solution test with a new unopened vial of strips.
- After following the appropriate steps and the control solution test result is out of range, do not perform a test. Please contact the infopia customer service at +82-31-460-0300 or sales@infopia21.com.
- The control solution range is not the recommended range for your test.
- Discard the used control solution and the test strips carefully according to the local regulations.

## Checking the system with LipidProfile check strip

### Check your Element® Multi meter with LipidProfile check-strip

- When your meter has a problem.
- Before first use.
- When the test results of Element® Multi are higher or lower than your symptoms.

#### Caution

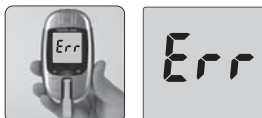
LipidProfile check strip test is no substitute for control solution test.



Insert LipidProfile check-strip and press ▲ and ▼ buttons at same time over 3 seconds. Check-mode will be operated.



If your meter is working properly, "000" will be displayed.



If your meter or check strip has a problem, "Err" will be displayed. Please contact your local representative, if "Err" persists.

#### Caution

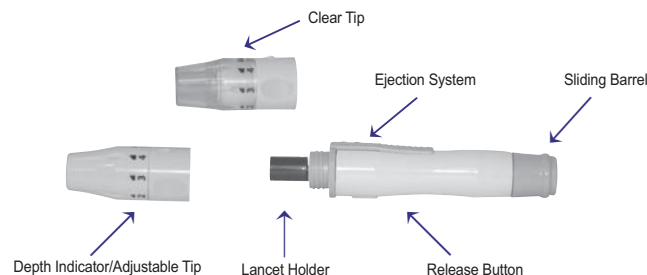
To get the accurate result, the meter should be checked in room temperature(23~25°C). Keep the LipidProfile check-strip out of direct sunlight for accurate test.

## INSTRUCTIONS FOR LANCING DEVICE

### PRECAUTIONS

- Never use a lancet that has been used by someone else. This could lead to contamination.
- If the lancing device is to be used by another person, the unit must be properly disinfected and a new tip and lancet must be used.
- Do not leave the lancet in the device after use.
- A new lancet must only be placed into the lancing device directly before testing.
- This device has many small parts and could be a choking hazard for children if swallowed.
- In the case of hospital use, hospitals need to consult their own infection control protocols in order to avoid any contamination.
- Always dispose of the used lancet in a biohazard garbage container.

### COMPONENTS



## HOW TO USE

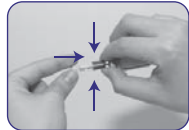
Wash your hands carefully with warm water to increase the circulation of the blood into the fingers.  
Dry hands thoroughly until the finger to be pricked is completely dry. Please read the following steps with corresponding illustrations to understand how to use the lancing device.



1. Unscrew the tip of the lancing device by turning it counter-clockwise while holding the base firmly.



2. With two fingers, pull out the lancet carrier and hold it in place.



3. While holding the lancet carrier, insert a new sterile lancet into the bottom of lancet carrier.



4. Twist the cap of the lancet off.



5. Put the tip of the lancing device back on and turn it clockwise.



6. Hold the tip firmly in one hand then pull out the sliding barrel with the other hand. This will cock the lancing device.



7. Place the lancing device in place. Hold the lancing device firmly against the side of the finger, with the cap resting on the finger. (The harder it is pressed, the deeper the puncture is.) Press the release button to take a sample.



8. Unscrew the tip of the lancing device by turning it counter-clockwise.



9. Push the lancet ejector forward with the thumb and simultaneously pull out the sliding barrel to dispose of the used lancet in a proper biohazard container.

## RECOMMENDED AVAILABLE LANCETS

Some general sterilized lancets are BD-Ultra Fine, Cleanlet Fine, E-Z Ject, G-P Lite, Microlet, Monolet, One Touch, Soft Touch, Therasense, Ultra TLC and Unilet GP, Gentlet.

Note: Some less known lancets may not work properly with the lancing device due to their dimensions.

Please, contact your supplier to make sure you are using proper lancets.

## Testing Your Blood - Preparation

### Blood testing

A strip instructions for use is included with each box of test strips. Please read the strip instructions for use along with this section completely and carefully before testing.

### Testing supplies



To perform a blood test you need:

- Element® Multi meter
- Test strips
- Sterile lancet
- Capillary rod
- Lancing device

### Caution

- 1) To reduce the chance of infection.
  - The lancing device and sterile lancets should NOT be shared with others.
  - Always use a new, sterile lancet.
  - Lancets are for single use only.
  - Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.
- 2) Do not operate the meter in direct sunlight.
- 3) Practice using the lancing device and become accustomed with its use.
  - Wash your hands with warm and clean water with soap. Dry your hands completely before testing.

## Testing Your Blood

### Caution

You may get an inaccurate result if the blood sample is not completely fill in a single action.

*Venouse whole blood and serum process for Profile test*

For venous whole blood and serum, acceptable anti-coagulants are EDTA, heparin and these samples may be stored at 4°C~20°C (39°F ~68°F) for three days.

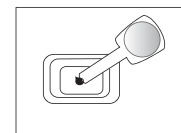
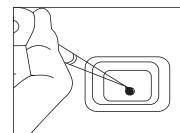
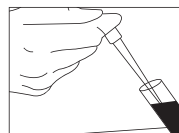
Please follow the procedure below.

1. Allow blood sample to reach room temperature.
2. Anti-coagulated blood should be mixed well prior to testing.
3. Remove the stopper from the holder and collect the sample by using pipette.

### Optional method

- Take out a drop of blood sample on a clean container.
- Apply your blood sample to the Element® Multi Profile strip and do not take off capillary rod until you get the beep sound. The test will automatically start.

4. Apply the sample to the test strip.



### Caution :

Do not freeze the samples, but store at 4°C instead and test quickly. Please test freshly collected samples. If the samples are not fresh, LPL(lipoprotein lipase) or LCAT(lecithin cholesterol acyltransferase) may affect the form of lipoprotein.

## Testing Your Blood

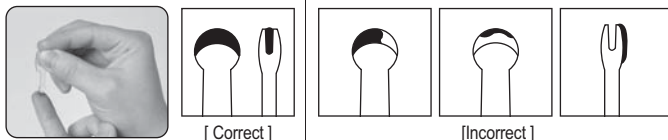
### Capillary blood process

#### Caution

You may get an inaccurate result if the blood sample is not completely fill in a single action.

#### 1. Cholesterol test

When you collect the sample, please use the capillary rod provided with the test strip package. Make sure enough sample has been collected to the capillary rod. Apply your blood sample to the Profile strip and do not take off capillary rod until you get the beep sound. The test will be started automatically.



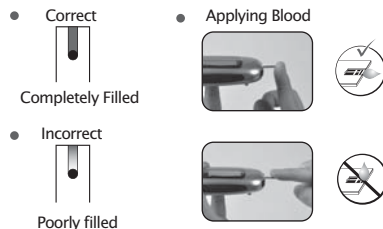
#### Caution

If blood is stained outside the sample area, carefully wipe the stain out with a tissue. Do not allow the wiping tissue to touch the open end of the sample area of the collecting leg.

#### 2. Glucose test

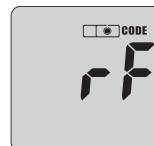


Place your fingertip to the top edge of glucose test strip and do not take off until you get the beep sound. The test will be started automatically.



## Test Procedure

### 1. Test for profile strips



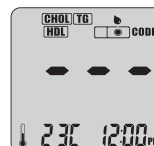
Insert a profile test strip and press mode ( ) button.



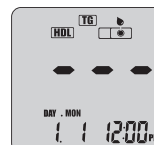
Place RFID-tag on the strip vial to the area of the RFID symbol ( ) on the meter.



Make sure the code number matches the code on the strip vial



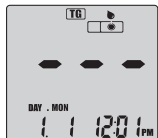
The meter displays the code number and the testing symbols ( **CHOL** , **HDL** , **TG** ) together. In 5 seconds the meter automatically enters into testing mode.



Please apply the sample to the total cholesterol test area of test strip until you hear beep sound. Then, the symbol, **CHOL** disappears.



## Test Procedure



Please apply the sample to the HDL-cholesterol test area of test strip until you hear beep sound. Then, the symbol, **[HDL]** disappears.



Please apply the sample to the triglyceride test area of test strip until you hear beep sound. Then, the symbol, **[TG]** disappears.



The meter displays ---, blinking in order, which means it is under test.



Total cholesterol is displayed with 3 times of buzzing sound.



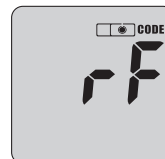
In the case of calculated LDL-cholesterol, if density of triglyceride is over 350mg/dL, it can't be measured.

In order to check each test item, please press up or down button. You can check out each result of Total Cholesterol, HDL-Cholesterol and Triglyceride.

## Test Procedure

### 2. Test for each single item

#### 1) Total Cholesterol test



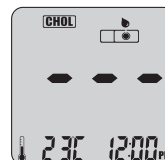
Insert a total cholesterol test strip and press mode ( ) button.



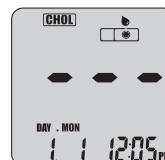
Place the RFID-tag on the strip vial to the area of the RFID symbol ( ) on the meter.



Make sure code number matches the code on the strip vial.

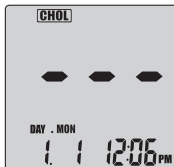


The meter displays the code number and the testing symbols ( **[CHOL]** ) together. In 5 seconds the meter automatically enters into testing mode.

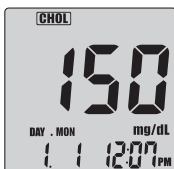


The symbol of blood is blinking.

## Test Procedure

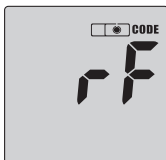


The meter displays **- - -**, blinking in order, which means it is currently undergoing tests.



When the test is completed (in 2 minutes), the meter displays the test result of **CHOL** with the symbol.

### 2) HDL-Cholesterol test



Insert a HDL-Cholesterol test strip and press mode ( ) button.



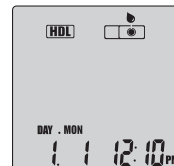
Place the RFID-tag on the strip bottle to the area of the RFID ( ) on the meter.



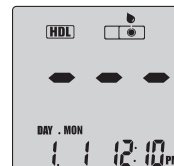
Make sure code number matches the code on the strip vial.

The meter displays the code number and the testing symbols ( **HDL** ) together. In 5 seconds the meter automatically enters into testing mode.

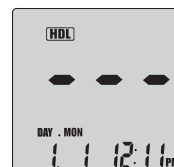
## Test Procedure



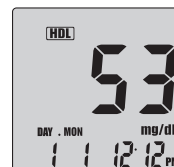
The symbol of blood is blinking.



Please apply the sample to the test area of test strip until you hear beep sound.



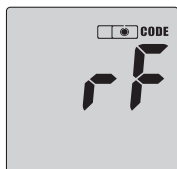
The meter displays **- - -**, blinking in order, which means it is under test.




When the test is completed (in about 2 minutes), the meter displays the test result of **HDL** with the symbol.


## Test Procedure

### 3) Triglyceride test




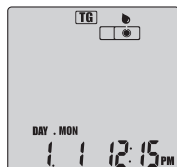
Insert a triglyceride test strip and press mode (  ) button.



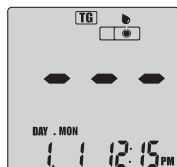
Place the RFID-tag on the strip bottle to the area of the RFID symbol (  ) on the meter.



Make sure code number matches the code on the strip vial.  
The meter displays the code number and the testing symbols (  ) together. In 5 seconds the meter automatically enters into testing mode.

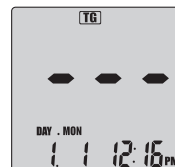



The symbol of blood is blinking.




Please apply the sample to the test area of test strip until you hear beep sound.

## Test Procedure



The meter displays , blinking in order, which means it is under test.



When the test is completed (in about 2 minutes), the meter displays the test result of  with the symbol.

## Test Procedure

### 3. Test for glucose



Firmly insert the glucose test strip into the test port of Element® Multi meter and then the power will automatically turn on with the code number, temperature and time.



Make sure code number on display of the meter correspond with that on the test strip vial. The color coding label of the back on the test strip automatically indicates the code number in this system.



The symbol of blood is blinking.



Once the sample is applied, the meter displays 3, 2, 1 in order.



Then, the meter completes the test with the test result.

#### Caution

1. If the code is not displayed after 3 seconds, pull the test strip out of the port and restart the procedure from the beginning.
2. If the codes on the display and that on the test vial do not match, try another new strip. If the mismatch persists, please contact your local representative for help.
3. If the meter does not power on, pull the test strip out of the port and re-insert the test strip.
4. Avoid testing under direct sunlight for more accurate test result.
5. If you apply your sample too early, error message will appear on the display (refer to page 47)

## Glucose test strip Discard Function



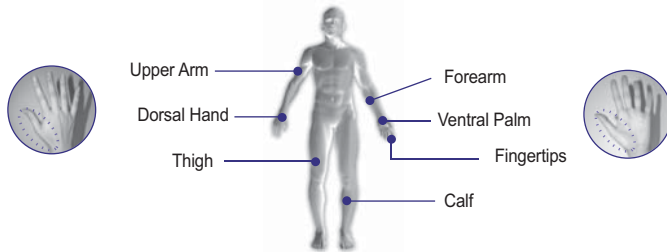
1. After checking your test result, turn the meter upside down and slide the ejector button twice forward to remove the test strip from the meter.
2. Discard the used strip and lancet to a proper place, according to the local regulation.

#### Caution

1. If you push the discard button forward too much, it may be damaged.
2. Do not give strong impact to meter.

## Alternate site testing at glucose measuring

**Note :** This alternate site testing is applied to glucose testing only.



### **Important Information About Using Alternate Sites Testing :**

- Alternate sites where you can test are dorsal hand, ventral palm, upper arm, forearm, calf, and thigh.
- Under certain conditions, blood glucose test results obtained using samples taken from your alternate sites may differ significantly from fingertip samples
- The conditions in which these differences are more likely to occur are when your blood glucose is changing rapidly such as following a meal, as insulin dose, or associated with physical exercise.
- When blood glucose is changing rapidly, fingertip samples show these changes more quickly than alternate sites samples.
- When your blood glucose is falling, testing with a fingertip sample may identify a hypoglycemic (low blood glucose) level sooner than a test with a alternate sites sample.
- Use alternate sites samples only for testing prior to or more than two hours after meal, insulin doses, or physical exercise.
- Testing performed within two hours after meals, insulin doses, or physical exercise or whenever you feel that your glucose levels may be changing rapidly should be done from the fingertip.
- You should also use fingertip testing whenever you have a concern about hypoglycemia (insulin reactions) such as when driving a car, particularly if you suffer from hypoglycemic unawareness (lack of symptom to indicate as insulin reaction), as forearm testing may fail to detect hypoglycemia.

## Performing a Blood Test using an Alternate site

### **Important :**

We recommend that you test on your fingertip if you are testing for hypoglycemia (low blood glucose) or if you have a history of reoccurring hypoglycemia.



To ensure accurate results when lancing your forearm, upper arm, hand, thigh, or calf, wash the test site with soap and water.

Make sure there is no cream or lotion on the test site.  
Thoroughly dry your hands and test site.

- Consult your healthcare professional(doctor) before you begin using the alternate site

### **Caution**

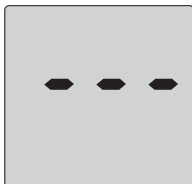
- To ensure accurate results when lancing your arm (Upper arm or forearm), leg (calf or thigh) or palm (ventral palm or dorsal hand), wash your hand and test site with soap and water.
- To receive accurate test results, 0.3µl minimum sample volume is required at least .

## Reviewing Your Results

Every test result is stored with its date and time of test.

The meter stores 200 memories regardless of test items.

When the test results is over the capacity memory, the recent test result will replace with the oldest test result.



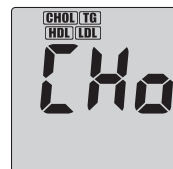
When there is no memory in the meter,  
— — — will be displayed.

## How to enter into Memory Mode

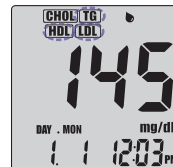
In order to enter into Memory mode, please press Up(▲) button at standby mode. By using Up(▲) or Down(▼) button you can recall cholesterol and glucose test results. Press the mode button after you select between profile and glucose test results you would like to review.

## Reviewing Your Results

### Profile test results



Press Mode ( ) button.

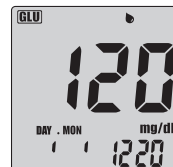


Press Up(▲) or Down(▼) button for reviewing the rest result.

### Glucose Test results



Press Mode ( ) button.



Press Up(▲) button and the meter displays the average data and the symbol ( **AVR** ) you had set previously. Please press ▲ or ▼ button for reviewing.

## Deleting Your Results



### Deleting individual test result

To delete any individual test result in the memory press ▲ or ▼ button for 3 or more seconds, while the test result to delete is displayed. Then, **dEL** is blinking. After the third beep sound, the test result is deleted. If the print is set "ON", press ▼ button in 3 or more seconds can be print memory results.



### Deleting all test results

To delete all results press ▲ and ▼ button at the same time for 3 or more seconds, while any test result is displayed. Then, **ALL** is displayed and **dEL** is blinking. After the third beep sound all test results are deleted.

## Printing Your Results



### Printing test results

Press ▼ button in 3 or more seconds can be print memory results. (If the print is set "ON")

#### Caution

The deleted test results can't be recovered. Please be careful in deleting the test results.

## Element® Multi Software and Thermal Printer

The Element® Multi results can be transmitted to a personal computer. Element® Multi software and an interface cable are required for transmitting results of Element® Multi profile and glucose measurement system to a personal computer. The software is available free of charge from <http://www.infopia21.com>.

Interface(PC)cable and Thermal printer can be bought from your local distributor.



The meter connects the interface cable to your PC or Printer. 'Con' on the LCD display



If Element® Multi connected interface cable to your PC (software is running). 'PC' on the LCD display



If Element® Multi connected interface cable to your Printer (Printer power On). 'Ptr' on the LCD display

## Cleaning Your Meter and Maintenance

### Meter

Your meter does not require special maintenance or cleaning. Avoid getting dirt, dust, blood, control solution, or liquids on the meter, the test port or data port. Your meter operation temperature is 18~30°C (64~86°F) for cholesterol and 10~40°C (50~104°F) for glucose.





It is recommended that you store the meter in its carrying case after each use. A cloth dampened with water and mild detergent can be used to wipe down the outside of the meter. Your Element® Multi meter is a precision instrument. Please handle it with care.

- 1) Do not disassemble or modify the meter.
- 2) Do not place the meter in places with high humidity.
- 3) Do not place the meter in polluted or dusty areas.
- 4) Do not expose the meter to impact, shock, vibration, inclination, etc. and keep it in a safe place.
- 5) Do not place the meter with chemical products or with gases.
- 6) Keep it away from direct sunlight.
- 7) Close the vial, immediately after taking out the test strip for the test.
- 8) Keep the test strip away from children.
- 9) Keep the lancing device clean by using alcohol or soap and water.
- 10) The meter should be cleaned with soft cloth or paper tissue, in case of dirt.

### Lancing Device:






Clean the lancing device and caps with soap and luke warm water. To disinfect the lancing device, prepare a disinfectant solution of one part household bleach to 10 parts water. Dampen a cloth with this solution and wipe the lancing device thoroughly. Soak only the cap for at least 30 minutes in the disinfectant solution. Do not soak the lancing device in liquid. Rinse the lancing device and cap with water and dry thoroughly. Properly discard the used lancet.

## Troubleshooting






Message	Probable cause	Action required
	This message appears when the hardware defects. Ex) The Flash ROM write/read function does not work. Oxidization voltage is out of range, etc.	Reboot the meter by placing the batteries again when no test strip is inserted. Please contact your local representative or customer support when the problem persists.
	This message appears when test strip may be contaminated or reused. (Only for Blood glucose measurement)	Please insert a new test strip and perform your test again.
	This message appears when the blood is not enough (Only for Blood glucose measurement)	Please insert a new test strip and apply the sufficient sample blood.
	This message appears when strip signals without any Blood or Control solution or other sample applying. (Only for Blood glucose measurement)	Please insert a new test strip and perform your test again.



## Troubleshooting

Message	Probable cause	Action required
	This message appears when blood sample is input before the symbol for blood blinks. (Only for Blood glucose measurement)	Please wait for the meter displays the icon blinking before applying your blood sample.
	This message appears when the color bar of the strip is dirty or not good or there is too much light.	Please insert a new test strip and perform your test again. Avoid testing under direct sunlight.
	This message appears when Element® Multi cholesterol test strip is removed during testing.	Test again with a new test strip and make sure the test strip to be inserted into the right port of each item. Do not move the test strip from the meter during the test.(If strip isn't removed, it says that your TC Result may be over 600mg/dL)
	Problem with transmit of PC or Printer.	Check your connection port of PC/printer and reconnection. If the problem is still unsolved, Please contact your local representative or customer support.
	The test result is higher than the following. Glucose : more than 600mg/dL TC : more than 400mg/dL TG : more than 600mg/dL HDL : more than 80mg/dL	Please retest with a new test strip. If the problem persists, please contact your local representative or customer support.

## Troubleshooting

Message	Probable cause	Action required
	The test result is lower than the following. Glucose : less than 20mg/dL TC : less than 100mg/dL TG : less than 70mg/dL HDL : less than 25mg/dL	Please retest with a new test strip. If the problem persists, please contact your local representative or customer support.
	Cholesterol : The ambient temperature is over 86°F(30°C). Glucose : The ambient temperature is over 104°F(40°C)	Place the meter at the temperature between 64~86°F(18~30°C) for cholesterol test and 50~104°F(10~40°C) for glucose test for more than 10 minutes and test again.
	Cholesterol : The ambient temperature is less than 64°F(18°C) Glucose : The ambient temperature is less than 50°F(10°C)	Place the meter at the temperature between 64~86°F(18~30°C) for cholesterol test and 50~104°F(10~40°C) for glucose test for more than 10 minutes and test again.
	This message appears when test strip may be contaminated, reused or not inserted.	Please insert a new test strip of cholesterol and perform your test again.
	This message appears with 3 times of beep sound with 'CODE' and 'Er' on the display are none memory code and/or unrecognized strip used.	Please recognize the code and retest (refer to page 23)

## Troubleshooting for Inconsistent or unexpected test results

If you continue to get unexpected results, check your system with control solution.

If you experience symptoms that are not consistent with your glucose and cholesterol results, Please make sure you have followed all instructions in this instructions for use. Then, contact infopia Customer Service. Never ignore symptoms or make significant changes to the control program.

## Product Specification

	Devison	Content
<b>Element® Multi Cholesterol Test</b>	Sample type	Capillary whole blood, Venous blood, Serum
	Testing types	Total cholesterol HDL-cholesterol Triglyceride LDL-cholesterol Calculated
	Testing method	Enzymatic-colorimetric method
	Testing range	Total cholesterol : 100~400mg/dL, Triglyceride :70~600mg/dL, HDL-cholesterol : 25~80mg/dL
	Testing time	2 minutes
	Calibration	Plasma - Equivalent
	Sample volume	5 $\mu$ l
	Operating humidity	10 ~ 90 %
	Operating temperature	18~30°C(64~86°F)
	Storage temperature	2 ~ 30°C(36 ~ 86°F)
	Hct range	30 ~ 55%

## Product Specification

	Devison	Content
<b>Element® Multi glucose test</b>	Sample type	Capillary whole blood
	Testing Types	Glucose
	Test range	10~600 mg/dL
	Sample volume	0.3 $\mu$ l
	Testing time	3sec
	Calibration	Plasma - Equivalent
	Operating humidity	10 ~ 90 %
	Operating temperature	10~40°C(50~104°F)
	Storage temperature	2 ~ 30°C(36 ~ 86°F)
	Hct range	20 ~ 60%
<b>RFID</b>	Standard supported	ISO/IEC 15693
	Nominal Read/write range	< 2cm
	Antenna	Integrated
	Frequency	13.56 MHz

## Product Specification

Devision	Content
Measuring principle	Electrochemical, Spectroscopy
Storage memory	200 measurement data
Operation temperature	Cholesterol : 18 ~ 30°C(64~86°F) Glucose : 10~40°C(50~104°F)
Operation humidity	10 ~ 90%
Display type	LCD
Size(W*D*H)	61 x 109 x 23 (mm)
Weight	77.5g (including battery) ± 1g
Power supply	DC (AAA) 1.5V x 2
Battery life time	Running over 1,000 times
PC port	For cable connection between PC and meter

## Warranty

### *Manufacturer's warranty:*

infopia Co., Ltd., warrants to the original purchaser that this instrument will be free from defects in workmanship for 3 years from the date of original purchase.

### *Limitations of warranty:*

This warranty is subject to the following exceptions and limitations:

1. infopia Co., Ltd. shall not be required to replace any unit which are damaged or malfunction due to abuse, accidents, alteration, neglect, misuse, maintenance by someone other than infopia Co., Ltd., or failure to operate in accordance with the instructions.
2. infopia Co., Ltd. reserves the right to make changes in design without obligation to incorporate such changes into previously manufactured instruments.
3. infopia Co., Ltd. has no knowledge of the performance of the instrument when the test strip is altered or modified in any manner.

















### *For warranty service :*

Purchaser must contact the local representative for assistance and/or instructions for obtaining service of this instrument.

### **Important:**

Speak to the infopia Co., Ltd. local representative before returning your instrument for any reason. She/he will give you the information needed to resolve your problem correctly and efficiently.

## Symbol Reference

Symbol	Description
	Serial number
	Consult operating instructions
	Used By
	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices
	Caution, consult accompanying documents
	For In Vitro Diagnostic Use
	Batch code
	Catalogue Number
	Temperature limitation
	Do not re-use
	Date of Manufacture
	Keep away from sunlight
	Separate collection for waste electrical and electronic equipment
	Self-Testing Used
	Manufacturer
	Authorized representative in the European Community